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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/533,362

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EXAMINER

CHAWLA, JYOTI

ART UNIT

PAPER NUMBER

1794

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/533,362	Applicant(s) VIRGALLITO ET AL.	
	Examiner JYOTI CHAWLA	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/29/05, 5/26/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Applicant's IDS submission of 4/29/2005 and 5/26/005 is acknowledged.

Claims 1-11 are pending and examined in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is indefinite for the recitation of "gelatin and or pectin", metes and bounds of the phrase are unclear. It is not clear whether pectin and gelatin are both required, or only one of gelatin or pectin is required by the claim as recited. Correction is required.

For the purposes of expediting the prosecution, presence of either gelatin or pectin in the edible film composition would be considered appropriate and a prior art comprising either gelatin or pectin would be regarded as relevant.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(1) Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al (WO 00/42992, IDS reference), hereinafter Chen.

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Regarding claim 1, Chen teaches an edible film composition for delivering an active agent to the oral cavity, the composition comprising a water-dispersible film-forming material selected from a cellulose ether and a starch, and a food acid (Page 3, lines 30 to page 4, line 6, Page 5, lines 8-12, Page 11, lines 17-26, Page 14, line 15 to page 15, line 3).

Regarding claim 2, Chen teaches of a film which contains food acids including citric acid, malic acid, tartaric acid, ascorbic acid, fumaric acid, lactic acid, (Page 11, lines 17-26), which are included in applicant's recited list of acids.

Regarding claim 3, applicant recites that the food acid is present in amounts of at least about 8 wt %. Chen teaches of applicant's recited acids as part of buffering agents as well as stabilizers (Page 11, lines 17-26). Regarding the concentration of acids, Chen teaches that the buffering agents can be 0.1-10% and stabilizing agents can be 0.01 to 5%, i.e., the total acidic component as taught by Chen can be 15% of the film composition (Page 15, line 12). Thus, Chen teaches of acid in the range recited by the applicant of at least about 8 wt % based on the dry weight of the composition.

Regarding claim 4, Chen teaches that the active agent is selected from a flavourant formulation, a therapeutic agent (i.e., a pharmaceutical agent), a dietary supplement (i.e., a nutraceutical agent) and hygiene aid and mixtures thereof (Page 4, lines 6-8 and Page 10, line 22 to Page 11, line 12).

Regarding claim 5, Chen teaches a composition wherein active agent is encapsulated in microcapsules that are dispersed throughout the film (page 7, lines 19-21 and Page 9, lines 13-15).

Regarding claim 6, Chen teaches a composition wherein more than one active agents are included in the film and are encapsulated (Page 7, line 18 to page 9, line 16), i.e., Chen teaches of microcapsules comprise a first population of microcapsules containing

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a first active ingredient, and a second population of microcapsules containing a second active ingredient.

Regarding claim 7, Chen teaches composition comprising pectin (Page 14, line 13).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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(A) Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen (WO 00/42992) in view of Dictionary.com Unabridged (v 1.1), definition of term wafer.

Chen has been relied upon to reject claims 1-5 and 7 under 35 USC 102(b) as discussed above.

Regarding claim 8, Chen teaches of thin film with active ingredient as recited in claims 1-7, which is die cut into different shapes and sizes. Chen also teaches that the film may be cut into single dosage unit and the size of the film may be varied according to the dosage required (Page 16, lines 2-6). Dictionary.com Unabridged(v 1.1) defines wafer as a thin disk of dried paste, gelatin, adhesive paper, or the like, used for sealing letters, attaching papers, etc. OR *Medicine/Medical*. A thin sheet of dry paste or the like, used to enclose a powder to be swallowed.

Thus, based on the definition a wafer is a thin disc of dried paste, which is a film cut into the shape of a disc. Since Chen teaches of a thin film, which is cut to different shapes and sizes, to deliver a single dosage of active ingredient, therefore, it would have been a matter of routine determination for one of ordinary skill in the art at the time of the invention to cut Chen's film into wafers at least for the reasons of personal preference and ease of cutting, packaging etc.

Regarding Claim 9, Chen teaches of a film, blend is extruded to form a film of selected thickness (Page 16, lines 11-13). The reference teaches of mixing all the ingredients and extruding, i.e., a monolayer, as instantly claimed.

Regarding Claim 10, Chen teaches of film thickness in the range of 1-20 mils and particularly less than 10 mils (Page 4, lines 17-19).

1 mil = 1/1000 inch, i.e., 1 mil is about 25 microns.

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Thus based on the above conversion factor, Chen's film thickness range is 25-500 microns, and preferably less than 250 microns, which includes applicant's recited range of thickness of 5 to 200 microns.

Regarding claim 11, Chen teaches of packaging (Figure 3, and Page 6, lines 4-8, items 16, 17, 18 and 19), wherein plurality of units or wafers are packaged as recited by the applicant.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 4, 5, 7, 9, 11 of current application 10/533362 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 6, 8, 11, 17-18 of copending Application No. 10/494442. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim edible film compositions with hydrocolloid forming ingredients and acids, where the active ingredient is microencapsulated and the monolayer thin film is packaged.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTI CHAWLA whose telephone number is (571)272-8212. The examiner can normally be reached on 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC
Examiner
Art Unit 1794

/KEITH D. HENDRICKS/
Supervisory Patent Examiner, Art Unit 1794